Contracting with the Government (including labs)

- Subcommittee on Technology and Procurement Policy, Chairman Tom Davis
  - Hearing on concerns of industry regarding IP, July 17, 2001
  - Intellectual Property and Government R&D for Homeland Security” May 10, 2002. House

Contracting with the Government

- Need to attract new contractors
- Existing flexibility within existing regulations
- Trained negotiators
- background rights
- Prime obtaining rights in subs IP
- March-in rights
- OT authority

Contracting with the Government: DOD

- DOD
  - Letter
  - IP guide
  - Training

DOE Missions

- Basic research: High energy physics, human genome, etc.
- Applied research to produce commercial technology: Clean Coal, FreedomCar, etc.
- Applied research to produce products for DOE use: Stockpile Stewardship, clean up, etc.

Contracting with the Government: DOE

- The blessings of laws: patent waivers and data dissemination
- Trained IP counsel available for all contracting elements including labs
- Flexibility: Class waivers, teaming IP, EPACT data, Background, Copyright of Software

Contracting with the Government: DOE

- Assistance: Grants and Cooperative Agreements
  - DOE does many large R&D Cooperative Agreements for energy research, teaming arrangements
  - 10 CFR 600 still requires DEAR IP clauses

Contracting with the Government: DOE

- 10 CFR proposed changes:
  - Separate coverage for For Profits: Checklist class waivers, no Background, automatic copyright, no Authorization and Consent
  - Univ. and Non profits: no Authorization and Consent, no separate DEAR coverage

Transactions with DOE Laboratories: Subcontracts

- Prudent Business practice with do respect for govt, requirements, subject to mandatory flow downs.
- IP follows DOE acquisition rules
- may be used for large R&D efforts Hybrid vehicles because of lab technical expertise
- competition followed but no formal right of appeal through government contract appeals.
- DOE sensitive to not having these transaction be used as a way to circumvent govt. rules. Cost sharing followed.

Transactions with DOE Laboratories: Subcontracts

- Where's the flexibility?
- DOE made me do it!

Lab dealing with DOE awardee

- DOE issues Cooperative Agreement to company
- Lab to be “subcontractor and do part of work
- CRADA? WFO?

DOE FOIA regulations:CVI

- 10 C.F.R. § 1004.3 provides:
  - (e) Contractor Records. (1) When a contract with DOE provides that any records acquired or generated by the contractor in its performance of the contract shall be the property of the Government, DOE will make available to the public such records that are in the possession of the Government or the contractor, unless the records are exempt from public disclosure under 5 U.S.C. 552(b)(2).

DOE FOIA regulations:CVI

- (2) Notwithstanding paragraph (e)(1) of this section, records owned by the Government under contract that contain information or technical data having commercial value as defined in § 1004.3(e)(4) or information for which the contractor claims a privilege recognized under Federal or State law shall be made available only when they are in the possession of the Government and not otherwise exempt under 5 U.S.C. 552(b).

DOE FOIA regulations:CVI

- (4) For purposes of § 1004.3(e)(2), "technical data and information having commercial value" means technical data and related commercial or financial information which is generated or acquired by a contractor and possessed by that contractor, and whose disclosure the contractor certifies to DOE would cause competitive harm to the commercial value or use of the information or data. 10 C.F.R. § 1004.3 (2001) (amended 1994).

DOE FOIA regulations:CVI

- (3) The policies stated in this paragraph:
  - (i) Do not affect or alter contractors' obligations to provide to DOE upon request any records that DOE owns under contract, or DOE's rights under contract to obtain any contractor records and to determine their disposition, including public dissemination; and

DOE FOIA regulations:CVI

- “The Deputy General Counsel stated that DOE’s mandate to disseminate information does not categorically require that all technical data first-produced must be released to the public in an unrestricted manner. In some circumstances, the Department has recognized that dissemination can be satisfied by making the benefits of the use of first-produced data available to the public. According to the Deputy General Counsel, _____ arrogated to itself, without consultation with DOE, the determination of how dissemination is satisfied.”

Lab Licensing of Data?

- Legal Mechanism exists: FOIA regulation, copyright clause
- Survey programs
- Pros and cons session with DOE field and labs
- TTWG

DOE March-in rights action

- Petition filed by Ventana addressed to Sec. asking that action be taken against UC per the DOE/UC contract for LLNL
- Two inventions made in mid 80's and waived to UC

Terms of waiver

- ***the Secretary or his designee shall have the right to terminate the waiver of the rights pertaining to the above-identified invention in whole or in part unless the Contractor demonstrates to the satisfaction of the Secretary or his designee that effective steps have been taken or within a reasonable time thereafter are expected to be taken, necessary to accomplish substantial utilization of the invention***.

Terms of waiver

- ***the Secretary or his designee shall have the right***, ***…to require the granting of a nonexclusive or partially exclusive license to a responsible applicant or applicants, upon terms reasonable under the circumstances, and in appropriate circumstances to terminate the waiver of rights pertaining to the above-identified invention, in whole or in part, following a hearing upon notice thereof to the public, upon a petition by an interested person justifying such hearing*** :

Terms of waiver

- ***if the Secretary or his designee determines, upon review of such material as he deems relevant, and after the Contractor or other interested person has had the opportunity to provide such relevant and material information as the Secretary of his designee may require***, that such waiver has tended substantially to lessen competition or result in undue market concentration in any section of the country in any line of commerce to which the technology of the invention relates; or

Terms of waiver

- unless the Contractor demonstrates to the satisfaction of the Secretary or his designee at such hearing that the Contractor has taken effective steps, or within a reasonable time thereafter is expected to take such steps, necessary to accomplish substantial utilization of the above-identified invention.

Background Facts

- Inventions are useful in identifying target gene sequences
- Applications filed in mid 80's but patents did not issue until 1995
- La's first licensee quit
- Exclusive license to Vysis
- On day patent issued, UC/Vysis sued ONCOR for infringement which was settled
- Ventana purchased some of ONCOR
- Vysis and Ventana were in negotiations for a license

Ventana allegations

- The exclusive license resulted in **undue market concentration and substantially lessened competition in the line of commerce** to which the technology relates"
- ."The Contractor **has not taken effective steps to accomplish substantial utilization of the invention**, nor is expected to do so"
- . "The DOE relied on a Request for Waiver that contained false material statements, and failed to disclose material facts in reaching the waiver determination"
- . "The Contractor has not given requisite **preference to small business firms** in licensing the inventions"

DOE initial action

- Initial review by AGC indicated further consideration required.
- Procedure modeled after 37 CFR 401.6 agreed to by all parties.
  - Fact Finder:AGC
  - Panel to decide whether to hold public hearing: DGC, sr. program, sr. policy

Process

- DOE repeatedly urged ADR
- Parties (Ventana, UC/Vysis) filed a series of briefs which included declarations from other interested parties and experts.
- parties appeared before Panel to present their positions and answer questions.
- Additional filings allowed even though not part of agreed upon procedure.
- Draft decision sent to parties for their comment
- Final decision issued

Final decision

- “Line of commerce” is diagnostic tests not probes for use by experimental laboratories
- FDA and DOJ consulted by DOE. Parties not permitted to cross examine but were permitted to comment on information obtained. Technology not a medial standard.
- European market examined: no patents there.
- Mere fact that there was just one exclusive licensee not enough to show **undue** market concentration or **substantial** lessening of competition. Exclusive license is an expected outcome from the waiver.

Final decision

- Vysis not making a profit yet. Demonstrated substantial private investment.
- Royalty free licenses offered to research labs.
- Ventana really saying that “potential” market is huge.
- Small business preference does not mean UC had to license a small business. Discretion to evaluate business plans.
- No further action should be taken by DOE

Final Decision: Other items

- Reasonable royalty rate not before panel. Issue only if DOE finds undue market concentration, etc.
- Filing of the infringement lawsuit is not evidence of an improper attempt to stifle competition.
- Long prosecution not a case of submarine patenting. DOE examined prosecution file. Filing of application not kept secret.
- “Through the filing of its Petition, Ventana is attempting to interject DOE into a private dispute over the terms of a license.”

Final Thoughts

- Initial petition filed June 22, 1999.
- Final Decision issued Dec. 21 2001.
- UC costs probably taken from royalties.